PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Jane P. Bearinger, et al.	Docket No. :	IL-11213
Serial No. :	10/781,582	Art Unit :	3731
Filed :	02/17/2004	Examiner :	Timothy J. Neal
For :	SYSTEM FOR CLOSURE OF A PHYSICAL ANOMALY		

Honorable Commissioner for Patents
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

Dear Sir:

APPELLANTS' BRIEF (37 C.F.R. § 1.192)

This brief is submitted in support of Appellants' notice of appeal from the Final Rejection mailed December 27, 2007 finally rejecting claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 of the subject application.

Appellants' notice of appeal was filed March 10, 2008.

One copy of the brief is being transmitted per 37 C.F.R. § 41.37.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is:

Lawrence Livermore National Security, LLC and the United States of America as represented by the United States Department of Energy (DOE) by virtue of an assignment by the inventor as duly recorded in the Assignment Branch of the U.S. Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

The application as originally filed contained claims 1-35.

The claims on appeal are claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35.

The status of all the claims in the proceeding (*e.g.*, rejected, allowed or confirmed, withdrawn, objected to, canceled) is:

Claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 are rejected.

Claims 2, 3, 7, 8, 9, 10, 22, 23, 24, 26, 27, 28, 29, 30, and 33 are cancelled.

Claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 on appeal are reproduced in the Appendix.

IV. STATUS OF AMENDMENTS

There are no amendments subsequent to the December 27, 2007 Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Appellants' invention provides an apparatus and a method for closure of a physical anomaly that forms a gap in a vascular wall. Appellants' invention provides a closure body made of a shape memory polymer (SMP) foam. The shape memory polymer (SMP) foam has at least one hard segment and one soft segment wherein the hard segment is formed at a temperature above T_{trans} and the soft segment is formed at a temperature below T_{trans}. Appellants' invention is illustrated in FIGS. 1, 2, 3, and 5B reproduced below and described in the portions of the specification quoted below.

> The present invention provides apparatus and methods for closure of a physical anomaly. The closure is provided by a polymer body with an exterior surface. The exterior surface contacts the opening of the anomaly and closes the anomaly. The polymer body has a primary shape for closing the anomaly and a secondary shape that allows it to be positioned in the physical anomaly. (Page 7, Lines 22-26 of Appellants' Specification)

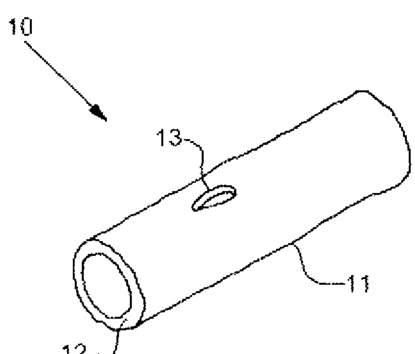


FIG. 1

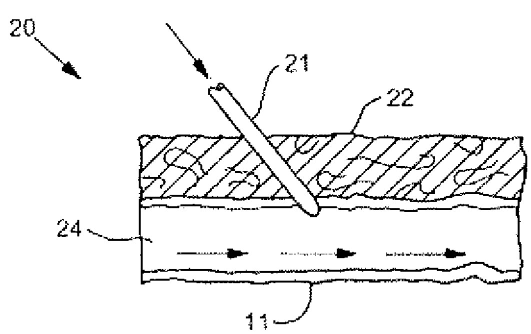


FIG. 2

> FIG. 1 is an isometric schematic of a puncture site 13 through the vessel wall 12 of a vessel 11. (Page 8, Lines 20-21 of Appellants' Specification) In order to close such sites, a closure body, in one embodiment a polymeric foam, is advanced to the puncture site in order to seal the site. (Page 9, Lines 5-6 of Appellants' Specification)

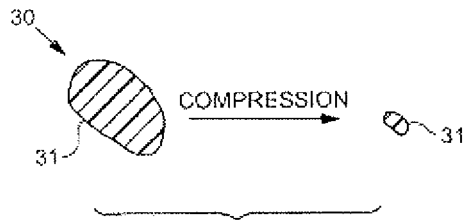


FIG. 3

FIG. 3 is a schematic of a closure body 31 in its expanded state and the closure body 31′ in its compressed state. The closure body 31′ is compressed to a smaller volume before deployment. (Page 10, Lines 15-17 of Appellants' Specification)

SMP foams comprise at least one hard segment and one soft segment. One segment contains a crosslinkable group; linking occurs via charge transfer, chemical or physical segment interactions. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment can return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, Lines 11-16 of Appellants' Specification)

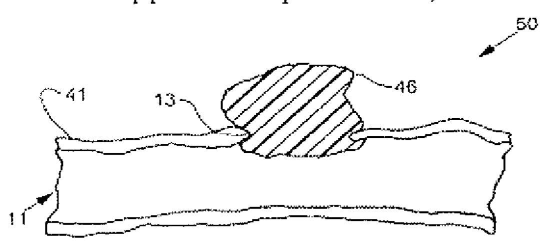


FIG. 5B

Full deployment of the SMP foam closure device is shown in FIG. 5B. The closure body 46 is shown in its expanded state (as opposed to compressed state) to fill the gap in the vessel wall in its entirety. In FIG. 5B, the puncture tract 45 is shown with the delivery catheter removed and with the closure body 46 in its expanded (actuated) state. (Page 13, Lines 24-26 of Appellants' Specification)

Appellants' independent claims 1, 19, and 32 involved in the appeal are "read on" Appellants' specification below. Portions of Appellants' specification are quoted and the paragraph containing the quote is identified by the page and line numbers.

Claim 1	Specification & Drawings
An apparatus for closure of a physical anomaly that forms a gap in a vascular wall, the apparatus comprising:	an apparatus for closure of a physical anomaly having a passage with the passage having an inner surface extending around the passage. (Page 4, lines 11-13) FIG. 1 is an isometric schematic of a puncture site 13 through the vessel wall 12 of a vessel 11. (Page 8, lines 20-21)
a closure body, said closure body made of a shape memory polymer (SMP) foam,	FIG. 3 is a schematic of a closure body 31 (Page 10, line 15) The closure body 31 and 31' is made of a shape memory material. (Page 10, lines 18-19) In another embodiment the polymer is a foam (Page 12, lines 8-8)
said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},	SMP foams comprise at least one hard segment and one soft segment. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment (Page 12, lines 11-15)
said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16)
said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)

Claim 1 (Continued)	Specification & Drawings
said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall, and	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16)
a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2) The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) delivery catheter comprises an actuation method to deploy the closure body 46 and allows it to reach its expanded (actuated) state. (Page 13, lines 8-9)
wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly.	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)

Claim 19	Specification & Drawings
A method of closing a physical anomaly that forms a gap in a vascular wall, the method comprising:	The present invention provides apparatus and methods for closure of a physical anomaly. (Page 7, lines 22-23) The embodiment 100, 100' can be used for the closure of punctures in vascular or non-vascular walls in the body. (Page 8, lines 7-8)
providing a closure body made of a shape memory polymer (SMP) foam,	FIG. 3 is a schematic of a closure body 31 (Page 10, line 15) The closure body 31 and 31' is made of a shape memory material. (Page 10, lines 18-19) In another embodiment the polymer is a foam (Page 12, lines 8-8)
said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},	SMP foams comprise at least one hard segment and one soft segment. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment (Page 12, lines 11-15)
said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16)
compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)

Claim 19 (Continued)	Specification & Drawings
positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall, and	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2) The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) delivery catheter comprises an actuation method to deploy the closure body 46 and allows it to reach its expanded (actuated) state. (Page 13, lines 8-9)
transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly.	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)

Claim 32	Specification & Drawings
A system for the closure of a physical anomaly that forms a gap in a vascular wall, the system comprising:	an apparatus for closure of a physical anomaly (Page 4, lines 11-12) FIG. 1 is an isometric schematic of a puncture site 13 through the vessel wall 12 of a vessel 11. (Page 8, lines 20-21)
a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam,	FIG. 3 is a schematic of a closure body 31 (Page 10, line 15) The closure body 31 and 31' is made of a shape memory material. (Page 10, lines 18-19) In another embodiment the polymer is a foam (Page 12, lines 8-8)

Claim 32 (Continued)	Specification & Drawings
said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},	SMP foams comprise at least one hard segment and one soft segment. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment (Page 12, lines 11-15)
said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall,	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)

Claim 32 (Continued)	Specification & Drawings
a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2) The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) delivery catheter comprises an actuation method to deploy the closure body 46 and allows it to reach its expanded (actuated) state. (Page 13, lines 8-9)
said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape; and	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2)
means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly.	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Final Rejection mailed December 27, 2007 states two grounds of rejection. The two grounds of rejection are summarized as follows:

Grounds of Rejection #1 - Claims 1, 4, 11, 16, 17, 19-21, 31, 32, 34, and 35 were rejected under 35 U.S.C. § 102(b) as being anticipated by Linden et al U. S. Patent No. 5,634,936 (hereinafter Linden). The rejection is stated on page 2 of the Final Rejection mailed December 27, 2007.

Grounds of Rejection #2 - Claims 1, 4, 11, 16, 17, 19-21, 31, 32, 34, and 35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Linden in view of Michlitsch U. S. Published Patent Application No. 2006/0155220 (hereinafter Michlitsch) and Langer et al U. S. Patent No. 6,388,043 (hereinafter Langer) or Kamiya et al U. S. Patent No. 5,192,301 (hereinafter Kamiya). The rejection is stated on pages 3-5 of the Final Rejection mailed December 27, 2007.

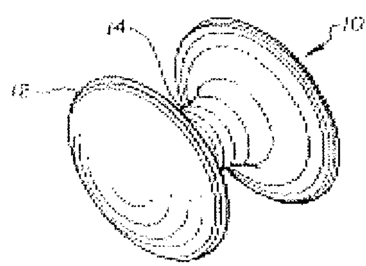
VII. ARGUMENT

Argument Relating to Grounds of Rejection #1 - Claims 1, 4, 11, 16, 17, 19-21, 31, 32, 34, and 35 were rejected under 35 U.S.C. § 102(b) as being anticipated by Linden.

The Linden Reference - The Linden reference is United States Patent No. 5,634,936 which is illustrated in FIGS. 2 and 4B reproduced below and described in the Linden specification as quoted below.

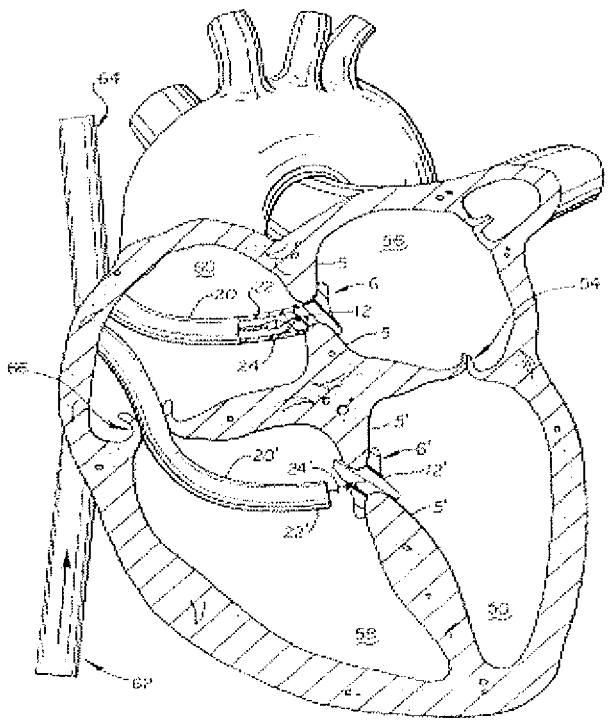
"The present invention relates generally to the closure of intravascular defects and more specifically to a device for closing a cardiovascular or cardiac septal defect, the device being made of a polymeric material delivered to the site of the defect by a catheter and hardened in-situ to a predetermined configuration to function as a plug."

Fig. 2



"As shown in FIG. 2, a device of the invention shown generally at 10 in one embodiment, is a preshaped plug 12 in the form of a disc with a narrower center portion 14. In this form, the device 10 serves as a plug 12 which is inserted into a tissue defect such as a septal defect. The polymeric material in this embodiment is ideally a polymeric self-hardening foam or sponge material which is soft and easily deformable so that it can be readily plugged into the defect. ... The plug 12 is made of a polymeric material in a specific conformation which reacts with a hardening agent after being installed in the septal defect to change the modulus of the material but not the preformed shape. As the material hardens, its modulus increases. .... The polymeric material may be a polyurethane foam formed from the mixture of isocyanates and polyols. Polyurethane foams are formed form the reactions of isocyanates and acids. As an example of such methylene diisocyanate reaction with polyvinyl acetic acid copolymerized with polyethylene oxide would cause the formation of a crosslinked polymer and the release of carbon dioxide, which would form the foaming agent..... In its deliverable form, plug 12 would preferably be bathed or presoaked in an organic solution or aqueous solution of a specific pH or ionic concentration. This is because the mechanism of hardening in this case resides with the transition or replacement of one fluid for another. For instance, a solution of water and DMSO (dimethylsulfoxide) at a specific pH would keep the polymer soft and contracted. Once the fluid is replaced by a second fluid at a different pH probably near physiological pH, or in contact with blood, the polymer expands and hardens."

Fig. 4b



"In FIG. 4b, plug 12 is shown being placed in ASD 6. Plug 12' is shown already in place in VSD 6' with catheter 20' in the process of being withdrawn. Plug 12 is delivered to the area of septal defect 6 by catheter 20 and inserted in place, centered in septal defect 6 as shown in FIG. 4b. Plug 12 may be either pulled or pushed out of catheter 20. Upon expulsion from its delivery system, plug 12 will assume its preformed shape in a narrow center portion with enlarged ends. Plug 12' is shown in place closing off ventricular septal defect 6', as corkscrew holder 24' and catheter delivery means 20' are being withdrawn."

"After its placement in the area of defect 6, plug 12 is hardened in-situ. The polymeric material may be hardened by alterations in pH effected by infusion through catheter 20 of a solution of pH differing from the pH of the original solution. Alternatively, the material may be hardened by the addition of an organic solvent or through dilution. Hardening may also be effected by permeation into the pores of the polymeric material of a secondary material delivered by the catheter that would precipitate with a change in pH or by the addition of a secondary material in gel form or solution."

Reversible Error - Linden Reference Does Not Anticipate Invention

The December 27, 2007 Final Rejection contains reversible error because it alleges the Linden reference contains all of Appellants' claim elements when in fact the Linden reference fails to disclose many of Appellants' claim elements. The standard for a 35 U.S.C. § 102 rejection is stated in RCA Corp. v. Applied Digital Systems, Inc, 221PQ 385, 388 (d. Cir. 1984) "Anticipation is established only when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention."

Appellants point out that the following elements of Appellants' amended claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 on appeal are not found in the Linden reference:

> Claim 1
> "a closure body, said closure body made of a shape memory polymer (SMP) foam," or
>
> "said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}," or
>
> "said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or
>
> "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or

"a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," or

"wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," or

"wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly," or

Claim 4
"actuator means for controllably actuating said shape memory polymer (SMP) foam having at least one hard segment wherein said hard segment is formed at a temperature above T_{trans} by changing said temperature above T_{trans}," or

Claim 17
"including actuator means for controllably actuating said shape memory polymer (SMP) foam, said actuator means configured to transition said closure body from said reduced secondary shape to said primary shape by changing said temperature above T_{trans} by heating," or

Claim 19
"providing a closure body made of a shape memory polymer (SMP) foam," or

"said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}," or

"said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or

"compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall," or

"transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly," or

<u>Claim 20</u>
"wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system that uses light, coherent light, or heat," or

<u>Claim 21</u>
"wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system chosen from the group consisting of external sheaths, removable sheaths, constraint sheaths, light, coherent light, heat, externally applied energy, plungers, RF, induction, stress, and combinations thereof," or

<u>Claim 31</u>
"wherein the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof and wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in said arteriotomy puncture sites, septal defects, patent ductus, or combinations thereof," or

Claim 32

"a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam," or

"said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}," or

"said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or

"a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," or

"said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall," or

"means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape," or

"means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly," or

Claim 34
"wherein said shape memory polymer (SMP) foam of said closure body with a secondary shape for being positioned in the physical anomaly and a larger primary shape for closing said anomaly, said shape memory polymer foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} and wherein said means for transitioning said closure body changes said temperature above T_{trans} by heating," or

Claim 35
"wherein said means for positioning said closure body in the physical anomaly in the vascular wall is a delivery catheter."

The Examiner's statement on Page 2, lines 12-14 of the Final Rejection "Linden discloses a closure body (12) made of a SMP foam having at least one hard segment and one soft segment wherein the hard segment is formed at a temperature above T_{trans} and the soft segment is formed at a temperature below T_{trans} (Column 4 Line 7, product-by-process limitation)" is an inaccurate and misleading characterization the Linden reference.

The quoted portion of the Linden reference does not disclose a closure body made of a SMP foam. The Linden reference only discloses a closure body made of a "polyurethane foam." See Column 4, line 31 of the Linden reference which states "may be ... a polyurethane foam."

The Linden reference does not disclose a <u>S</u>hape <u>M</u>emory <u>P</u>olymer foam. The quoted portion of the Linden reference does not disclose "a SMP foam having at least one hard segment and one soft segment wherein the hard segment is formed at a temperature above T_{trans} and the soft segment is formed at

a temperature below T_{trans}" as alleged in the Final Rejection. The Linden reference only discloses a "hardenable foam." The quoted portion (Column 4 line 7) of the Linden reference is reproduced below for reference.

> In another embodiment, the device may comprise a plug-like body of hardenable foam, gum or sponge-like material. (Column 4 line 7)

Since the elements described above are not found in the Linden reference, the Linden et al reference does not support a 35 U.S.C. § 102(b) rejection of Appellants' claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 on appeal and the rejection should be reversed.

Argument Relating to Grounds of Rejection #2 - Claims 1, 4-6, 11-17, 19-21, 31, 32, 34, and 35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Linden in view of Michlitsch and Langer or Kamiya.

The Linden Reference

The Linden reference is described above.

The Michlitsch Reference

The Michlitsch reference is United States Published Patent Application No. 2006/0155330 which is illustrated in FIGS. 4A and 34B reproduced below and described in the portions of the specification quoted below.

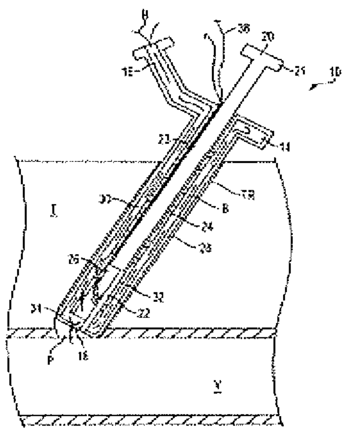


FIG. 4A

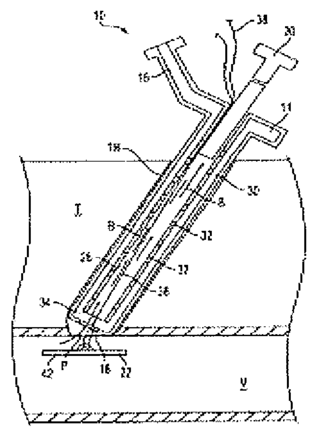


FIG. 4B

"Apparatus (**10**) is provided for sealing a vascular puncture tract by forming the autologous plug within the puncture tract, and extruding that plug into the puncture tract. The apparatus of the present invention forms an autologous blood plug by drawing blood into the apparatus from a vessel, mixing a blood congealing agent with the drawn blood, and ejecting a plug formed from the clotted blood within the puncture tract. Also provided are various closure elements (**22**) to isolate the drawn blood from the vessel during mixture with the blood congealing agent, and to facilitate placement of the apparatus relative to the vessel."

The Langer Reference

The Langer reference is United States Patent No. 6,388,043 which is illustrated in FIGS. 1 and 2 reproduced below and described in the portions of the specification quoted below.

FIG. 1

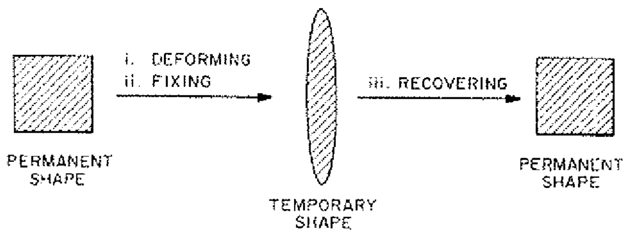
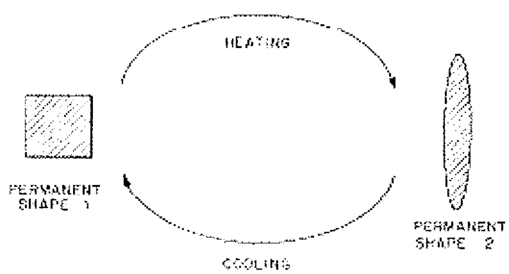


FIG. 2

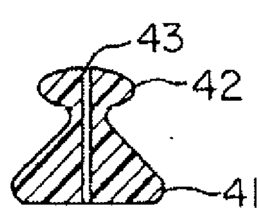


"Shape memory is the ability of a material to remember its original shape, either after mechanical deformation (FIG. **1**), which is a one-way effect, or by cooling and heating (FIG. **2**), which is a two-way effect. This phenomenon is based on a structural phase transformation."

The Kamiya Reference

The Kamiya reference is United States Patent No. 5,192,301 which is illustrated in FIG. 4 reproduced below and described in the portions of the specification quoted below.

F I G. 4



"FIG. 4 shows a closing plug having a flange part 41 and an additional flange part 42 at the apex of the cone. The second flange part 42 at the apex of the cone prevents the closing plug from falling off from the

> defect during pulse variation. The closing plug of FIG. 4 also has an elongated hole 43 therethrough which may be passed over a guide wire as explained above.

Prima Facie Case of Obviousness Has Not Been Established

The rejection of claims 1, 4-21, 25, 31, 34, and 35 under 35 U.S.C. § 103(a) is respectfully traversed. The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). To establish a *prima facie* case of obviousness, three basic criteria must be met. The prior art reference (or reference when combined) must teach or suggest all the claim limitations. The Examiner must provide reasons for combining the references (Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision). There must be a reasonable expectation of success. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In assessing any *prima facie* conclusion of obviousness the guidance of the Supreme Court in Graham v. John Deere Co. is used. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) requires determining: "the scope and content of the prior art," ascertaining "the differences between the prior art and the claims at issue," and resolving "the level of ordinary skill in the pertinent art."

Reversible Error - References Do Not Teach All Claim Limitations

The criteria that prior art reference (or reference when combined) must teach or suggest all the claim limitations has not been met. The Linden reference, the Michlitsch reference, the Langer reference, and the Kamiya reference do not disclose many Applicants' claim limitations. The Linden reference, the Michlitsch reference, the Langer reference, and the Kamiya reference do not disclose the limitations of Applicants' claims 1, 4-21, 25, 31, 34, and 35 identified below.

> Claim 1
> "a closure body, said closure body made of a shape memory polymer (SMP) foam," or
>
> "said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}," or
>
> "said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or
>
> "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or
>
> "said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or
>
> "a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery

device adapted to deploy said closure body into the physical anomaly in the vascular wall," or

"wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," or

"wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly," or

<u>Claim 4</u>
"actuator means for controllably actuating said shape memory polymer (SMP) foam having at least one hard segment wherein said hard segment is formed at a temperature above T_{trans} by changing said temperature above T_{trans}," or

<u>Claim 6</u>
"wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement," or

<u>Claim 17</u>
"including actuator means for controllably actuating said shape memory polymer (SMP) foam, said actuator means configured to transition said closure body from said reduced secondary shape to said primary shape by changing said temperature above T_{trans} by heating," or

<u>Claim 19</u>
"providing a closure body made of a shape memory polymer (SMP) foam," or

"said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}," or

"said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or

"compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall," or

"transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly," or

Claim 20
"wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system that uses light, coherent light, or heat," or

Claim 21
"wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system chosen from the group consisting of external sheaths, removable sheaths, constraint sheaths, light, coherent light, heat, externally applied energy, plungers, RF, induction, stress, and combinations thereof," or

Claim 25
"wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger," or

Claim 31
"wherein the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof and wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in said

arteriotomy puncture sites, septal defects, patent ductus, or combinations thereof," or

Claim 32

"a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam," or

"said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}," or

"said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or

"a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," or

"said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall," or

"means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape," or

"means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above

the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly," or

Claim 34
"wherein said shape memory polymer (SMP) foam of said closure body with a secondary shape for being positioned in the physical anomaly and a larger primary shape for closing said anomaly, said shape memory polymer foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} and wherein said means for transitioning said closure body changes said temperature above T_{trans} by heating," or

Claim 35
"wherein said means for positioning said closure body in the physical anomaly in the vascular wall is a delivery catheter."

The Examiner's statement on Page 3, lines 12-22 of the Final Rejection regarding the Linden reference is an inaccurate and misleading characterization the Linden reference. The Examiner's statement on Page 3, lines 12-22 of the Final Rejection is quoted below.

> "Linden discloses a closure body (12) made of a SMP foam having at least one hard segment and one soft segment wherein the hard segment is formed at a temperature *above* T_{trans} *and the soft segment is* formed *at a* temperature *below* Ttrans (Column 4 Line 7, product-by-process limitation), a primary shape (Figure 2), compressed into a reduced secondary shape (Figure 3), a delivery device being a catheter (20), an actuator means (Figure 4b), biodegradable polymers (Abstract), isocyanates (Column 6 Line 10), actuator means changing the temperature of the *closure* body *above* T_{trans} (Abstract). Linden also discloses positioning *the* closure *body* in a physical anomaly being a septal defect (Figure 4b)."

The quoted portion of the Linden reference does not disclose a closure body made of a SMP foam. The Linden reference only discloses a closure body

made of "polyurethane foam." See Column 4, line 31 of the Linden reference which states "may be ... a polyurethane foam."

The Linden reference does not disclose a Shape Memory Polymer foam. The quoted portion of the Linden reference does not disclose "a SMP foam having at least one hard segment and one soft segment wherein the hard segment is formed at a temperature above T_{trans} and the soft segment is formed at a temperature below T_{trans}" as alleged in the Final Rejection. The Linden reference only discloses a "hardenable foam." The quoted portion (Column 4 line 7) of the Linden reference is reproduced below for reference.

> In another embodiment, the device may comprise a plug-like body of hardenable foam, gum or sponge-like material. (Column 4 line 7)

Contrary to the statement in the December 27, 2007 Final Rejection, the Linden reference does not disclose "a primary shape (Figure 2), compressed into a reduced secondary shape (Figure 3)," as showing the claim limitation of Appellants' claims "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall."

The statement in the December 27, 2007 Final Rejection that the Linden reference discloses "a delivery device being a catheter (20), an actuator means

(Figure 4b), biodegradable polymers (Abstract), isocyanates (Column 6 Line 10), actuator means changing the temperature of the closure body above T_{trans} (Abstract)" is an inaccurate and misleading characterization the Linden reference. The Linden reference does not disclose actuator means changing the temperature of the closure body above T_{trans}. More importantly the quoted portion of the statement in the December 27, 2007 Final Rejection is not a showing that the Linden reference shows the claim limitation of Appellants' claims "a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall."

Contrary to the statement "Linden also discloses positioning *the* closure *body* in a physical anomaly being a septal defect (Figure 4b)" in the December 27, 2007 Final Rejection, the Linden reference does not disclose Appellants' claim limitation: "said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall, wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the

vascular wall, and wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly.

Since the claim limitations listed and described above are not shown by the Linden reference, the Michlitsch reference, the Langer reference, or the Kamiya reference a *prima facie* case of obviousness has not been established. Further, since the four references fail to show the claim limitations of Applicants' claims 1, 4-21, 25, 31, 34, and 35 there can be no combination of the four references that would show Applicant's invention. There is no combination of the Linden reference, the Michlitsch reference, the Langer reference, and the Kamiya reference that would produce the combination of elements of Applicants' claims 1, 4-21, 25, 31, 34, and 35. Thus, the combination of references in the December 27, 2007 Final Rejection fails to support a rejection of claims 1, 4-21, 25, 31, 34, and 35 under 35 U.S.C. § 103(a), and the rejection should be reversed.

No Reasons for Combining Linden, Michlitsch, Langer, and Kamiya

The criteria that the Examiner must provide reasons for combining the references (Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision) has not been established. The

rejection in the December 27, 2007 Final Rejection does not provide an explanation of how or why the Linden reference, the Michlitsch reference, the Langer reference, and the Kamiya reference would be combined.

The Linden reference, the Michlitsch reference, the Langer reference, and the Kamiya reference do not recognize the problem solved by Appellants' claimed invention. The four cited references fail to disclose the benefits of Applicants claimed invention "providing a closure body made of a shape memory polymer (SMP) foam, said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans}, said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall, compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall, and transitioning said closure body made of a shape memory polymer (SMP) foam to said primary

shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly." Thus, the combination of references in the December 27, 2007 Final Rejection fails to support a rejection of claims 1, 4-21, 25, 31, 34, and 35 under 35 U.S.C. § 103(a), and the rejection should be reversed.

SUMMARY

Appellants have shown that Grounds of Rejection #1 and #2 contain reversible error. It is respectfully requested that the rejections be reversed and claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 on appeal be allowed.

Respectfully submitted,

By: Eddie E. Scott

Eddie E. Scott
Lawrence Livermore National Laboratory
7000 East Avenue, Mail Code L-703
Livermore, CA 94550
Attorney for Appellants
Registration No. 25,220
Telephone No. (925) 424-6897

Date: May 5, 2008

VIII. CLAIMS APPENDIX

1. An apparatus for closure of a physical anomaly that forms a gap in a vascular wall, the apparatus comprising:

a closure body, said closure body made of a shape memory polymer (SMP) foam,

said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},

said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall, and

a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,

wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and

wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly.

4. The apparatus of claim 1 including actuator means for controllably actuating said shape memory polymer (SMP) foam having at least one hard segment wherein said hard segment is formed at a temperature above T_{trans} by changing said temperature above T_{trans} .

5. The apparatus of claim 1 wherein said delivery device includes a tube and a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall.

6. The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement.

11. The apparatus of claim 1 wherein said delivery device is a delivery catheter.

12. The apparatus of claim 1 wherein said delivery device includes a plunger actuator.

13. The apparatus of claim 1 wherein said delivery device includes a backbleed tube.

14. The apparatus of claim 1 wherein said delivery device includes a plunger actuator and a delivery catheter.

15. The apparatus of claim 1 wherein said delivery device includes a delivery catheter, a plunger actuator, and a restraint tube.

16. The apparatus of claim 1 wherein the physical anomaly is an arteriotomy puncture site.

17. The apparatus of claim 1 including actuator means for controllably actuating said shape memory polymer (SMP) foam, said actuator means configured to transition said closure body from said reduced secondary shape to said primary shape by changing said temperature above T_{trans} by heating.

19. A method of closing a physical anomaly that forms a gap in a vascular wall, the method comprising:

providing a closure body made of a shape memory polymer (SMP) foam,

said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},

said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,

compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,

positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall, and

transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by

heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly.

20. The method of claim 19 wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system that uses light, coherent light, or heat.

21. The method of claim 20, wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system chosen from the group consisting of external sheaths, removable sheaths, constraint sheaths, light, coherent light, heat, externally applied energy, plungers, RF, induction, stress, and combinations thereof.

25. The method of claim 19 wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger.

31. The method of claim 19 wherein the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof and wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the

vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in said arteriotomy puncture sites, septal defects, patent ductus, or combinations thereof.

32. A system for the closure of a physical anomaly that forms a gap in a vascular wall, the system comprising:

a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam,

said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},

said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall,

a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,

said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall,

means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape; and

means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly.

34. The system for the closure of a physical anomaly of claim 32 wherein said shape memory polymer (SMP) foam of said closure body with a secondary shape for being positioned in the physical anomaly and a larger primary shape for closing said anomaly, said shape memory polymer foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} and wherein said means for transitioning said closure body changes said temperature above T_{trans} by heating.

35. The system of claim 32 wherein said means for positioning said closure body in the physical anomaly in the vascular wall is a delivery catheter.

IX. EVIDENCE APPENDIX

There are no entries in the Evidence Appendix.

X. RELATED PROCEEDINGS APPENDIX

There are no entries in the Related Proceedings Appendix.